



Europäisches Patentamt
European Patent Office
Office européen des brevets



⑪ Publication number:

0 621 017 A1

⑫

EUROPEAN PATENT APPLICATION

㉑ Application number: 94302929.8

㉑ Int. Cl. 5: A61F 2/06

㉒ Date of filing: 25.04.94

㉓ Priority: 23.04.93 US 52410

㉑ Applicant: ADVANCED CARDIOVASCULAR

SYSTEMS, INC.

3200 Lakeside Drive

Santa Clara California 95052 (US)

㉔ Designated Contracting States:

BE CH DE FR GB IT LI NL

㉒ Inventor: Khosravi, Farhad

2208 Ewell Drive

Belmont, CA 94002 (US)

Inventor: Williams, Michael S.

9311 Laurel Springs Drive

Chapel Hill, NC 27516 (US)

㉕ Date of publication of application:

26.10.94 Bulletin 94/43

㉔ Representative: Mayes, Stuart David et al

BOULT, WADE & TENNANT

27 Furnival Street

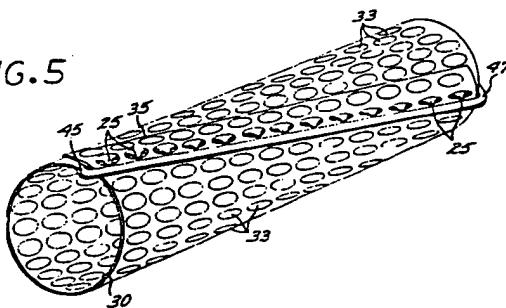
London, EC4A 1PQ (GB)

㉖ Ratcheting stent.

㉗ An intravascular stent comprising a cylindrical sheet having overlapping edges that interlock. The edges have a series of protrusions and apertures (33) that interlock and ratchet as the stent expands to an open position to support a section of arterial wall. The stent may be expanded by a balloon catheter or it may be self-expanding. The stent is biocompatible, may be bio-erodible, and capable of localized drug delivery.

carbon or by structural reinforcement as in composite laminates.

FIG.5



EP 0 621 017 A1

The intravascular stent may be made of a sheet

BACKGROUND OF THE INVENTIONField Of The Invention

The present invention generally relates to expandable endoprosthesis devices, in particular to expandable intraluminal vascular grafts, generally called stents, adapted to be implanted into a body lumen, such as a coronary artery, to maintain the patency of the lumen. These devices frequently are used in the treatment of atherosclerotic stenosis in blood vessels, especially after percutaneous transluminal coronary angioplasty (PTCA) procedures, with the intent of helping to reduce the likelihood of restenosis of a blood vessel. Stents also are used to support a body lumen where a flap or dissection has occurred or, in general, where the lumen is weak. The present invention also relates to an expandable intraluminal vascular graft that can be used in any body lumen.

Description Of Related Art

In expandable stents that are delivered with expandable catheters, such as balloon catheters, the stents are positioned over the balloon portion of the catheter and expanded from a reduced diameter to an enlarged diameter greater than or equal to the diameter of the artery wall, by inflating the balloon. Stents of this type can be expanded to an enlarged diameter by deforming the stent, by engagement of the stent walls with respect to one another, and by one-way engagement of the stent walls together with endothelial tissue growth into the stent. Other stents are self-expanding, by virtue of the properties of the material constituting the stent or by other aspects of the design.

SUMMARY OF THE INVENTION

According to a first aspect of the present invention there is provided an intraluminal stent implantable in a body lumen, comprising: a plurality of rings having at least a pair of overlapping edges; a plurality of teeth on at least one of said overlapping edges; whereby said rings are expanded from a first diameter to an adjustable, enlarged diameter so that said teeth engage in an interlocking relationship to hold said rings in said enlarged diameter form.

Advantageously the stent has a longitudinal axis, and further comprises a longitudinally extending portion connecting said rings to one another. Preferably one of said overlapping edges has at least one slot and the other of said overlapping edges has at least one tab, said tab engaging said slot to form said interlocking relationship. Preferably said slot contains said teeth. Preferably said

teeth in said slot are connected to adjacent teeth transverse to said teeth in said slot. Alternatively, said tab contains said teeth.

Advantageously the stent has a longitudinal axis, wherein said overlapping edges spiral along said longitudinal axis in a helical manner.

Advantageously the stent is formed of a polymer material coated with a thin strengthening material comprising a pyrolytic carbon.

According to a second aspect of the present invention there is provided an intraluminal stent implantable in a body lumen, comprising: a cylindrical body portion formed of a sheet having longitudinally extending overlapping edges; a plurality of tabs located on one edge of said sheet; a plurality of slots on said sheet corresponding with and aligning with said tabs; whereby said slots receive said tabs.

Advantageously the stent further comprises a plurality of teeth on said tabs. Preferably the stent further comprises a plurality of teeth lined inside said slot.

Advantageously the stent further comprises means for retaining said cylindrical body portion in said first diameter position until it is expanded to said second, enlarged diameter. Preferably said means for retaining said cylindrical body portion in said first diameter position comprises a plurality of breakaway tabs along one edge of the stent.

Advantageously the cylindrical body portion has a plurality of apertures for increasing the flexibility of the stent. Preferably said apertures are in the form of a plurality of elongated apertures transversely aligned with said cylindrical body.

Advantageously said plurality of tabs is connected by a reinforcing member to prevent unintentional disengagement of the tabs from said slots.

Advantageously the stent further comprises a crescent-shaped aperture at one end of each of said plurality of slots for receiving a corresponding tab.

Advantageously the stent is formed of a polymer material coated with a thin strengthening material comprising a pyrolytic carbon.

Accordingly to a third aspect of the present invention there is provided an intraluminal stent implantable in a body lumen, comprising: a cylindrical body portion having an axial length extending along a longitudinal direction, said cylindrical body portion formed of a sheet having a first longitudinal edge and a second longitudinal edge, an elongated slot in said sheet on said first longitudinal edge, said elongated slot adapted to receive said second longitudinal edge.

Advantageously the stent further comprises means for interlocking said first and second longitudinal edges. Preferably said means for inter-

locking said first and second longitudinal edges comprises a plurality of teeth adjacent each edge adapted to engage in an interlocking relationship. Preferably said teeth slant along the cross-sectional circumferential direction of said cylindrical stent in opposite directions.

Advantageously said cylindrical body portion has a plurality of apertures for increasing the flexibility of the stent.

Advantageously said cylindrical body portion is expanded from a first diameter to a second, enlarged diameter, wherein said means for interlocking said first and second longitudinal edges comprises a plurality of teeth on said first longitudinal edge and a plurality of corresponding apertures adjacent said second longitudinal edge, said teeth and apertures engaging in an interlocking relationship to retain said stent in said second, enlarged diameter.

Advantageously the stent is formed of a polymer material coated with a thin strengthening material comprising a pyrolytic carbon.

According to a fourth aspect of the present invention there is provided an intraluminal stent implantable in a body lumen, comprising: at least one strip disposed along a longitudinal direction, said strip forming a ring having overlapping edges; a slot disposed in said stent, said slot receiving said strip to form said ring.

Advantageously the stent further comprises a pair of breakaway tabs connecting said stent ring at said overlapping edges, to maintain the stent in a reduced diameter form during transport of the stent through a vasculature.

Advantageously the stent further comprises a plurality of said strips interconnected to one another to form said stent. Preferably said strips have edges that are serrated, said serrated edges passing through said slot. Preferably said serrated edges comprise sawtooth edges, and said edges engage and are held by said slot. Preferably said slot contains teeth. Preferably said teeth in said slot are joined in a breakaway manner.

Advantageously the stent is formed of a polymer material coated with a thin strengthening material comprising a pyrolytic carbon.

According to a fifth aspect of the present invention there is provided an intraluminal stent implantable in a body lumen, comprising: a substantially cylindrical body portion having a length extending along a longitudinal direction, said body portion having a first edge that contains a slot extending along said longitudinal direction, and said body portion having a second edge extending along said longitudinal direction; said second edge passing through said slot; wherein when said cylindrical body portion is expanded from a first reduced diameter to a second, enlarged diameter,

said at least one of said edges undergoes greater deformation than said other edge, to create a bias so that said stent is biased to return to said first reduced diameter form.

- 5 Advantageously said cylindrical body portion has a plurality of apertures, and said first edge contains a plurality of teeth, wherein said teeth engage said apertures in an interlocking relationship.
- 10 Advantageously said body portion is formed from a reticulated structure comprising a plurality of substantially S-shaped members having a top portion and a bottom portion, said top and bottom portions extending along said longitudinal direction, and said S-shaped members connected to one another through a plurality of interconnecting members attached to said top and bottom portions of said S-shaped members. Preferably said S-shaped members are interconnected to one another to form a repetitive pattern of said S-shaped members in said sheet.
- 15
- 20

Advantageously the stent is formed of a polymer material coated with a thin strengthening material comprising a pyrolytic carbon.

- 25 According to a sixth aspect of the present invention there is provided an intraluminal stent implantable in a body lumen, comprising: a body portion formed from a sheet, said sheet having a first edge and a second edge parallel to said first edge, said sheet having a plurality of apertures near said first edge of said sheet and a plurality of teeth extending from said second edge of said sheet, said body portion having a substantially cylindrical shape, wherein said teeth engage said apertures, wherein said substantially cylindrical body portion has an axial length extending along a longitudinal direction, and said sheet is formed from a reticulated structure having a plurality of substantially S-shaped members, said S-shaped members having top and bottom portions, said top and bottom portions extending along said longitudinal direction, with said S-shaped members connected to one another through a plurality of interconnecting members attached to said top and bottom portions of said S-shaped members.
- 30
- 35
- 40
- 45

Advantageously said S-shaped members are interconnected to one another to form a repetitive pattern of said S-shaped members in said sheet. Preferably said repetitive pattern comprises a helical spiral of said S-shaped members about said longitudinal axis.

- 50 According to a seventh aspect of the present invention there is provided an intraluminal stent implantable in a body lumen, comprising a body portion formed from a sheet, said sheet having a first edge and a second edge parallel to said first edge, said sheet having a plurality of apertures near said first edge of said sheet and a plurality of
- 55

teeth extending from said second edge of said sheet, said body portion having a substantially cylindrical shape, wherein said teeth engage said apertures in an interlocking manner, wherein said substantially cylindrical body portion has an axial length extending along a longitudinal direction, said sheet is formed from a reticulated structure comprising a plurality of substantially honeycomb-like members, with a plurality of gaps interrupting said honeycomb-like members to allow increased flexibility.

Advantageously said gaps extend along a direction in said sheet substantially orthogonal to said longitudinal direction of said stent.

Advantageously said gaps spiral about said longitudinal direction in a helical manner.

Advantageously the stent is formed of a polymer material coated with a thin strengthening material comprising a pyrolytic carbon.

According to an eighth aspect of the present invention there is provided an intraluminal stent implantable in a body lumen, comprising a substantially cylindrical body portion having an axis extending along a longitudinal direction, said body portion formed from a sheet of material, said sheet having a pair of edges that form a spiral seam about said longitudinal direction.

Advantageously at least one of said edges has a plurality of projections extending therefrom, wherein said projections engage said sheet of material.

Advantageously said sheet of material is formed from a reticulated structure comprising a woven mesh.

Advantageously said sheet of material formed from a reticulated structure comprises a plurality of box-like members, and said projections comprise a plurality of hooks. Preferably said sheet has a substantially parallelogram shape.

Advantageously the stent is formed of a polymer material coated with a thin strengthening material comprising a pyrolytic carbon.

Thus it can be seen that the present invention is directed to a stent, adapted to be inserted within a body lumen, and designed to expand and lock in an enlarged diameter form.

The stents are designed to engage in a sure manner, and, once engaged, to stay engaged with a high degree of reliability.

In some embodiments of the stent the stent is locked along its seam by a locking member analogous to a "buckle." This buckle also may serve as a means for aligning the edges.

In another embodiment of the stent, a helical seam employing teeth is used, so that failure of the stent along the locking portion will not result in catastrophic failure of the stent to maintain patency. In yet another embodiment, a plurality of

reticulated structures are used to form the stent.

The stent may be made of a variety of materials, including biocompatible and bio-resorbable (bio-erodible) polymers, thermal-shaped memory polymers or metals, biocompatible metals, or super elastic materials such as nickel-titanium alloys. A material constituting the stent can be a thin, flexible polymer material, such as a polyimide, coated with a thin strengthening material comprising a pyrolytic carbon.

The stents are designed for flexibility coupled with radial strength.

The stent may be deployed in a body lumen through a variety of devices, including but not limited to balloon catheters and specialized stent delivery catheters.

BRIEF DESCRIPTION OF THE DRAWINGS

FIG. 1 shows a portion of a sheet forming the stent of one embodiment of the present invention.

FIG. 2 shows a cross-sectional view taken along a plane perpendicular to the longitudinal axis of the stent of FIG. 1, when the stent is rolled up in a reduced diameter form.

FIG. 3 shows a cross-sectional view taken along a plane perpendicular to the longitudinal axis of the stent, when the stent is unrolled in an expanded diameter form.

FIG. 4 shows a perspective view of an embodiment of the present invention.

FIG. 5 shows a perspective view of another embodiment of the present invention, showing the locking seam offset along a helical spiral.

FIG. 6 shows another embodiment of the present invention, showing a sheet forming the stent, prior to being rolled up to form the stent.

FIG. 7 shows a perspective view of a stent formed by the sheet of Fig. 6

FIG. 8 shows an embodiment of the present invention showing a portion of a stent-forming sheet having apertures and projections.

FIG. 9 shows a perspective view of a stent formed by the sheet of Fig. 8

FIG. 10 shows an embodiment of a stent-forming sheet employing a reticulated, box-like configuration.

FIG. 11 shows a close-up view of a sheet employing reticulated, S-shaped members.

FIG. 12 shows an embodiment of the present invention using a reticulated, honeycomb-like structured sheet material having horizontally-spaced gaps to allow increased flexibility.

FIG. 13 shows an embodiment of the present invention using a reticulated, honeycomb-like structured material having transversely-spaced gaps to allow increased flexibility.

FIG. 14 shows an embodiment of the present invention using a parallelogram-shaped reticulated structured stent-forming material having a helical locking seam with a plurality of hook-shaped members on the helical seam.

FIG. 15 shows an enlarged portion of the sheet of FIG. 14.

FIG. 16 shows a cross-sectional view of an embodiment of the present invention employing overlapping edges engaged by teeth.

FIG. 17 shows an enlarged view of the edge of a stent portion.

FIG. 18 shows a perspective view of a stent of the Fig. 17 embodiment.

FIG. 19 shows a view of a stent-forming sheet of material employing locking tabs.

FIG. 20 shows a perspective view of an embodiment of the present invention formed from the sheet of Fig. 19.

FIG. 21 shows a view of a stent-forming sheet of material employing a parallelogram shape.

FIG. 22 shows a perspective view of another stent, employing a ring-like configuration.

FIGS. 23-26 show laid out views of other embodiments of stent-forming sheets.

FIG. 27 shows a perspective view of a stent-forming sheet of another embodiment of the present invention.

FIG. 28 shows a perspective view of a stent formed with the sheet of Fig. 27.

FIG. 29 shows a cross-sectional view of the stent of Fig. 28.

DETAILED DESCRIPTION

As shown by Figs. 1-4, a flat sheet or membrane of material 10 is formed with an oval-shaped mesh pattern in the body portion 15 of the sheet. One end of body portion 15, buckle portion 20, includes a pair of rows of teeth 25 and an outer loop portion 30. The sheet is formed into a substantially cylindrical shaped stent by passing the bottom end 35 through the outer loop portion 30 of buckle portion 20. Teeth 25 then engage oval-shaped apertures 33, which form a mesh pattern.

As seen in Figs. 2, 3 and 4, the bottom end 35 is threaded through buckle portion 20, which forms a loop or slot extending along the longitudinal axis of the stent, and has loop ends 45, 47. In Fig. 2 the stent is shown in a reduced diameter form, and in this form the stent is placed on a stent delivery catheter to be transported to a site in a vessel that the stent is to be deployed. The stent is then expanded to an enlarged diameter form for deployment, as shown in Fig. 3.

Operation of the stent will now be described. The stent is placed over the stent delivery catheter that has been prepared for PTCA angioplasty. The

catheter is percutaneously introduced into a vessel, following a previously positioned guidewire in an over-the-wire angioplasty catheter system, and tracked by a fluoroscope, until the balloon portion and associated stent are positioned at the point where the stent is to be placed. The balloon is then inflated and the stent is expanded by the balloon portion from a reduced diameter form to an expanded diameter form. After the stent has been expanded to its final expanded diameter, the balloon is deflated and the catheter is withdrawn, leaving the stent in place. As is appreciated by those skilled in the art, the stent while being transported is of a sufficiently small, reduced diameter as to allow it to be readily transported through a vessel. Buckle portion 20 keeps the rows of teeth 25 engaged with apertures 33, at a suitable angle of engagement, to help prevent misalignment and incorrect engagement.

Fig. 4 shows a perspective view of this locking feature of this embodiment of the present invention, while Fig. 5 shows a perspective view of a substantially parallelogram disposed sheet forming this embodiment of stent, employing a helically extending slot buckle. The helically extending slot insures that the stress loads are directed in a direction anti-parallel to the longitudinal axis of the stent, which helps prevent catastrophic failure.

A material constituting any embodiment of the stent can be a thin flexible polymer material, such as a polyimide, coated with a strengthening material comprising a pyrolytic carbon. The pyrolytic carbon coating preferably is only about one angstrom (10^{-10} m) thick, which does not increase the cross-sectional profile of the stent in any appreciable manner, yet provides for increased tensile strength, stiffness, and resistance to radial compression. Furthermore, the pyrolytic carbon layer is anti-thrombogenic. This material can not only be employed in the stent embodiment shown in Figs. 1-4, but also may be employed in all embodiments of stents disclosed herein. Furthermore, in all of the embodiments of stents disclosed herein the material comprising the stent may be made of a biodegradable material, and may be a material impregnated with a drug, so the stent may locally treat a particular lesion or disease.

Expansion of stent 10 from a reduced diameter form into an expanded diameter form is preferably performed by a balloon catheter. Any other means for expanding the stent, however, may be used. Furthermore, the present stent is not limited to use in coronary arteries and over-the-wire angioplasty catheter systems. The stent may be deployed in any body lumen by any suitable means.

Another feature of the embodiment of Figs. 1-4 is the spiral shape assumed by the cross-section of the stent when it is rolled up in a reduced diameter

form as shown in Fig. 2. When the stent is expanded from a reduced diameter form, as shown in Fig. 2, to an expanded diameter form, as shown by Fig. 3, end 35 is deflected by a greater angle of rotation and/or translation than is buckle end 20, due to the geometry and composition of the wound up stent. This results in end 35 undergoing more deformation than end 20. Consequently end 35, and the bottom portion of the body portion 15, desires to return to its original reduced diameter shape more readily than buckle end 20 and the top buckle portion of body 15, which makes the stent resiliently biased radially inward. The stent thus is biased to return to its reduced diameter form. This resiliency helps teeth 25 engage apertures 33 more completely. The bias feature can be built into all suitable embodiments of the present invention.

Turning attention now to the embodiment of Figs. 6 and 7, there is shown a sheet of material 50, in substantially the shape of an elongated parallelogram, having sides 60, 62, with side 60 having a plurality of projections 55 extending from the side. Sheet 50 may be formed of any suitable material, and may be woven, textured or contain apertures like the embodiment of Fig. 1. Sheet 50 is wound into an elongated cylinder, with the sides 60, 62 overlapping and forming a helical seam 64 spiralling about the longitudinal axis of the stent. Projections 55 engage the material and maintain the stent in an enlarged diameter form, when the stent is expanded in the manner described above.

Fig. 8 shows another embodiment of the present invention. A substantially rectangular sheet 70 is formed with a plurality of apertures 75. On longitudinal edge 85 there are a plurality of projections 80 that engage apertures 75 when the stent is rolled up. As shown in Fig. 9, when the sheet is rolled up into a cylindrical stent, the edges of the sheet overlap along the longitudinal axis of the stent and projections 80 engage apertures 75 to lock the stent in an expanded diameter form, to resist collapse of the stent back into a reduced diameter form. The stent may be made of the same material as the embodiment of Fig. 1.

Turning attention now to Figs. 10 and 11, there is shown another embodiment of the present invention. A sheet of material 90 constituting the stent is made up of a reticulated structure employing S-shaped bars 95 that are linked with one another by interspaced linking bars 100 at the top and bottom portions of the S-shaped bars. At the edge of sheet 90 is a row of teeth 105 that form locking projections to engage the apertures in sheet 90 when the sheet is rolled into a cylindrical shape to form the stent. As can be seen from Fig. 10, the placement of the linking bars 100 along the S-shaped bars 95 and the spacing of the S-shaped bars 95 about one another may be a repeating pattern, such as a

pattern that achieves a substantially spiral pattern of S-shaped bars about the stent longitudinal axis, insuring flexibility. The reticulated structure shown may be employed in all embodiments of the present invention.

Turning attention to Figs. 12 and 13, there are shown alternate embodiments of the present invention disclosing reticulated structures having honeycomb-like cells with gaps interrupting the honeycomb-like cells in the reticulated structures to increase flexibility. In Fig. 12, sheet 110 has a plurality of honeycomb-like cells 115 that end at edge 120 in a row of locking teeth 122, which function as in the above embodiments to hold the stent open in an enlarged diameter form. In addition, horizontally spaced gaps 125 in the honeycomb cells 115 allow increased flexibility when sheet 110 is rolled up into a cylindrical form with overlapping edges extending along a longitudinal direction. The gaps 125 extend along the horizontal direction orthogonal to the longitudinal direction of the sheet, which extends along the longitudinal axis of the stent. When the stent is formed from the honeycomb like sheet gaps 125 form a series of bars interspaced along the longitudinal axis. Likewise as shown in Fig. 13, sheet 130 has a plurality of honeycomb like cells 135 that end at the edge in two rows of locking teeth 137, with the addition of diagonally slanted gaps 140 to allow increased flexibility. The diagonally slanted gaps 140 form a spiral configuration along the longitudinal axis of the stent.

Turning attention to Figs. 14-15 there is shown another embodiment of the present invention. A parallelogram-shaped reticulated sheet 150 is made up of box-shaped cells that end along one edge in a series of locking members, hooks 152. The sheet 150 is rolled into a cylindrical form, as in the embodiment shown in Fig. 7. Like the embodiments of Figs. 5 and 7, one advantage of a helically extending longitudinal seam over a non-helically extending longitudinal seam is that in the event of a failure, a break or tear between the locking members and the sheet will not propagate along the longitudinal direction in as readily a manner as when the load is distributed over a non-helical interface. In addition, the helical locking seam appears to distribute the load along the locking member interface in a more stable manner than a non-helical locking seam.

As shown by Fig. 16, a sheet or membrane of material 160, which may be any material suitable for a vascular prosthesis or stent, is formed with protrusions or teeth 165 on both sides of the edges of the sheet. As the sheet is rolled up to a cylindrical shape the upper edge 170 will become the inner surface 170 of the cylindrical stent and the lower edge 175 will become the outer surface 175

of the stent.

The protrusions are in the form of rows of individual teeth. In general the protrusions may be formed in any shape and in any manner, including but not limited to machining, etching, thermo-curing process, injection molding, laser machining, extruding, casting and adding the protrusions to a smooth body made of the same or different material from the protrusions, or treating the body to create a roughened surface texture. In one embodiment, the teeth are arranged in a substantially orderly, spaced arrangement of rows. In addition, the stent may be made directly into a cylindrical shape without first forming a flat sheet.

As can be seen from Fig. 16, the stent is formed from a rolled-up cylinder of material having overlapping longitudinal edges 180, 185, which lie along the longitudinal axis of the cylinder in a substantially parallel manner. Edge 185 fits through buckle slot 210, which serves as both a locking component and an alignment component. Teeth 165, 175 on each overlapping edge are slanted or sloped in opposite directions to each other, to form a one-way locking arrangement that resists collapse of the stent to a smaller diameter once the teeth are engaged. The stent is configured so it inherently tends to roll up into a smaller diameter, but is prevented from doing so by the interlocking teeth.

When the teeth are engaged with one another, the slope of the teeth allows the stent to be unrolled to an enlarged diameter much more readily than the stent can be collapsed to a rolled-up, reduced diameter. The cooperation of the teeth lock the stent in an expanded diameter form.

Operation of the stent will now be described. The stent is expanded from a reduced diameter, which is the state the stent is in while it is being transported through the vasculature, to an expanded diameter, which is the state the stent is in when operationally deployed in the vasculature. As is appreciated by those skilled in the art, the stent while being transported is of a small, reduced diameter sufficient to allow it to be readily transported through a body lumen. In this reduced diameter form, the stent is a rolled cylindrical sheet with overlapping edges, but teeth 165, 175 are not in contact with each other. When the stent is expanded from its reduced diameter to its enlarged diameter, the teeth would engage each other and the stent locks in an operational manner to function as a prosthesis.

Expansion of the stent from a reduced diameter to an expanded diameter is preferably performed by a balloon catheter or other mechanical means. Any other means for expanding the stent, may be used, however, including reliance on expansive properties of the material of the stent itself,

which may be made of a memory material such as Nitinol™, Elastin™, or other superelastic materials. Furthermore, it should be understood that the present stent is not limited to use in coronary arteries and angioplasty catheter systems, but the stent may be deployed in any body lumen by any suitable means.

Briefly and in general terms regarding the use of a balloon catheter to deploy the stent, when the stent is to be deployed in a coronary artery, the stent is placed over and mounted on the balloon portion of a catheter that has been prepared for PTCA. The catheter is introduced percutaneously into a body lumen, following a previously positioned guidewire in an over-the-wire angioplasty catheter system, and is tracked by a fluoroscope, until the balloon portion and associated stent are positioned at the point where the stent is to be placed. Thereafter, the balloon is inflated and the stent is expanded by the balloon portion from a reduced diameter to an expanded diameter. After the stent has been expanded to its final expanded diameter, the balloon is deflated and the catheter is withdrawn, leaving the stent in place.

Superelastic materials, such as nickel-titanium alloys (Ni-Ti), also may be used as a stent material for the present invention. Such superelastic material stents are self-expanding and eliminate the need to expand the stent through balloon dilatation or other mechanical means. Deployment of the stent made of a superelastic material could be achieved by confining the stent to a minimum diameter, for example, by enclosing the stent with a sheath while it is in its reduced diameter form, and allowing the stent to expand by retracting the sheath when it is desired to deploy the stent in an operational, expanded diameter form, by retracting the sheath. In this case the expansion of the stent occurs due to the inherent properties of the material constituting the stent. The properties of these superelastic materials are known by those skilled in the art.

Similarly, thermal shape memory polymers or metallic materials may be used as a stent material for another similar kind of self-expanding stent. These thermal memory stents have a transition temperature set at a value such that, at a normal body temperature, the stent is in a collapsed (plastically deformed) state, but with the application of heat, such as via a hot balloon catheter or a hot liquid (such as saline) in a perfusion system, the stent would expand by itself to assume its final diameter in the body lumen.

Stainless steel, tantalum, gold, platinum or another biocompatible metal, such as suitable tungsten alloys, also may be used as a material for the stent of the present invention.

The stent may be made of a bioabsorbable material, allowing the stent to dissolve. Such materials include, but are not limited to, polymers of the linear aliphatic polyester and glycolide families. The stent also may be made of a material having a lubricious coating such as silicone so that it has less resistance during deployment. These materials may also contain or be impregnated with various drugs, so that the stent may be used as a localized drug delivery device. The drugs impregnating the stent may include enzymes to prevent blood coagulation, or medication to prevent hyperplastic response from a blood vessel or body passageway or reduce the likelihood of restenosis.

Other materials contemplated for the stent embodiments of the present invention include biocompatible polymers, such as of the type from the polyethylene, polyester and polypropylene families and plastics such as a polymer from the linear aliphatic polyester family, such as poly(lactic acid), poly(glycolic acid) or polycaprolactone, and their associated copolymers, degradable polymers such as polyorthoester, polyanhydride, polydioxanone and polyhydroxybutyrate.

Turning now to Fig. 17, there is shown a protrusion pattern for the longitudinal edge of the stent of the present invention. A stent made according to the Fig. 17 embodiment has its teeth formed of triangular ridges 190, formed to extend along longitudinal rows extending along the length of the stent, to form a serrated longitudinal edge. Both the inner and outer sides of the cylindrical sheet forming the stent have such serrated edges.

Thus, as shown in Fig. 18, the triangular ridges lying on the inner surface of the stent would protrude radially inwardly toward the center of the cylindrical stent, and would lie on the outermost, overlapping, longitudinal edge 195 of the stent, the edge overlying innermost longitudinal edge 200. Likewise the triangular ridges that lie on the outer surface of the stent would protrude radially outwardly away from the center of the cylindrical stent. As before, the triangular ridges on both the innermost and the outermost longitudinal edges are sloped to resist collapse of the stent to a reduced diameter after it has been expanded to its larger diameter.

In addition, there exist apertures 205 in the stent to allow endothelial tissue growth into the stent, blood tissue interaction, access for side-branch patency, and as an aid for mechanical flexibility. The stent can have more or fewer apertures than depicted, or none at all, depending upon the desired application.

Yet another embodiment of the invention is depicted in Figs. 19 and 20. An intraluminal stent 240 has a plurality of tabs 245 along edge 250 of the stent. Each of tabs 245 has a plurality of teeth

255 adapted to engage teeth 260, which are located along the edges of elongated slots 265.

Each of tabs 245 and elongated slots 265 are aligned on the stent so that tab 245 can be inserted in crescent-shape aperture 270 of the slot. When the tab is properly positioned in the elongated slot, the teeth 255 on the tabs engage and interlock with the teeth on elongated slot 265, thereby locking the stent in a cylindrical form at a specific, yet easily, adjustable diameter. In order to prevent tabs 245 from unintentionally disengaging a reinforcing member 263 may be affixed to all of the tabs after the stent is rolled. Furthermore, a pair of breakaway tabs 275 may be used to connect the sheet at its overlapping edges while the stent is being transported, to maintain the stent in a reduced diameter form and preserve a minimal profile during transport of the stent through a vasculature. Such breakaway tabs may be employed in all embodiments of stents of the present invention.

The deployment of stent 240 in a patient is much the same as previously described. The intraluminal stent is collapsed to a first diameter onto the balloon portion of a balloon catheter and delivered to the site of deployment in the manner previously described.

When the balloon portion of the catheter is inflated, stent 240 will correspondingly expand radially outwardly until it comes in contact with that portion of the body lumen where it is to be deployed. As the stent 240 radially expands, retaining tabs 275 will break away and permit the stent to expand proportionately. The teeth 255 on tabs 245 will ratchet along teeth 260 of elongated slots 265 and will engage in an interlocking manner once expansion is completed. The inherent tendency of the intraluminal stent to close, as well as any force exerted by the walls of the body lumen on the outside of the stent, are sufficient to maintain teeth 255 and teeth 260 in an interlocking relationship so that the intraluminal stent maintains its form as cylindrical body 280.

Intraluminal stent 240 may have a plurality of elongated apertures 285 to allow endothelial tissue growth into the stent, blood tissue interaction, access for side-branch patency, and to provide for mechanical flexibility. If the stent is positioned in a particularly tortuous vessel or in a curved area, it is desirable that the stent be able to flex somewhat along its longitudinal length so that the ends of the stent do not irritate the vessel wall. Flexibility also is desirable to improve the ability to deliver the stent. Elongated apertures 285 facilitate the flexibility of the stent in curved areas. Apertures 285 may take many geometric shapes and still accomplish the desired objectives. For example, the apertures may be a plurality of laser pinholes randomly

spaced throughout the stent material.

Fig. 21 discloses another embodiment of stent that employs stent material 290 of a parallelogram shape and uses triangular notches (295) as apertures to both grip the stent and encourage endothelial tissue growth. In this embodiment the stent when rolled has a helically spiralling seam, by nature of its parallelogram shape.

As previously stated with respect to other embodiments, the intraluminal stent can be made of plastics, metals, and superelastic materials as described. Further, the intraluminal stent can be impregnated with various drugs, may be bio-compatible and/or bio-erodible.

In another embodiment of the invention, the stent can be in the form of one or more rings rather than a cylinder. It is contemplated that a plurality of rings could operate either independently of one another, either singularly or plurality in a side-by-side fashion, or, the rings could be interconnected to one another.

For example, as shown in Fig. 22, an embodiment of the present invention depicts stent 300 having a first longitudinal edge 305 and a second longitudinal edge 310. First longitudinal edge 305 comprises an elongated slot 315 that is slightly wider than the width of second longitudinal edge 310. A plurality of teeth or protrusions 325 extend substantially the entire length of the stent ring. There may be fewer teeth than is depicted in FIG. 22, depending upon the use of the stent and the nature of the body lumen in which it will be deployed. Tooth geometry may vary widely.

Stent 300 is coiled or rolled-up into a cylindrical configuration by inserting second longitudinal edge 310 through elongated slot 315 and sliding the stent onto the balloon portion of a catheter so that it has a low profile for transport through a body lumen. When the stent is positioned at the location where it is to be deployed, the balloon portion of the catheter is expanded, as previously described with other embodiments, until the stent comes in contact with the arterial wall. As the stent expands to its larger diameter, teeth 325 engage the edges of slot 315, in a ratcheting manner, until the stent is fully expanded. As previously described, the stent has a tendency to return to its coiled configuration and is prevented from doing so by the interlocking relationship between teeth 325 and slot 315. As can be appreciated, the geometric shape of that portion of the stent surrounding elongated slot 315 may take any shape. Further, the dimensions of the stent can vary depending upon the application. As also can be appreciated, but not shown in the drawing figures, stent 300 may have a plurality of apertures that would increase its flexibility so it could be placed in a tortuous area of a coronary artery.

Other embodiments of sheets forming ring stents are shown in Figs. 23 and 24. As can be seen from the figures, the ring stents are either interconnected (Fig. 23) or spaced from one another in a zig-zag or sinusoidal fashion (Fig. 24). If the ring stents are spaced from one another, as in Fig. 24, the edges 340 may be tapered, so that if the rings stents overlap, the profile may be kept at a minimum. It should be noted that the stent of Fig. 23, as any of the stent embodiments of the present invention, may employ a breakaway tab 345 to maintain the stent in a reduced diameter form during transport of the stent through a vasculature, with the tab breaking when the stent is expanded during deployment. In addition, the stent of Fig. 23 may have teeth 350 joined together in a unitary construction, for better structural integrity, with the teeth breaking apart when tab 355 is inserted into slot 360 and the stent expanded.

Another embodiment of stent employing a single stent ring is shown in Fig. 25. Here one or more teeth 370 engages one or more protrusions 375 inside of a slot-like portion of the stent.

Yet another example of a stent employing a plurality of rings is depicted in FIG. 26. A plurality of strips or stent rings 380 are formed from a sheet of material, with the stent rings 380 having along their edges teeth 385. The stent rings are formed by passing ends 390 through slots 395, whereupon the stent is formed into a cylindrical shape having a plurality of stent rings joined at tab portion 400. The stent so formed is able to be expanded to a plurality of different size diameters along its axial length, because the stent rings 380 can be expanded to various diameters independent of one another, as they are joined only a connecting tab portion 400. The stent thus formed may be made more flexible. Furthermore, breakaway tabs may be employed to keep the stent in a collapsed state until such time that the stent is to be deployed, at which time the stent may be expanded and the breakaway tabs broken.

In another embodiment of the invention, depicted in Figs. 27-29, an intraluminal stent 410 is depicted as a flat sheet and in its rolled-up cylindrical configuration. A first longitudinal edge 415 has a slot 420 adjacent the edge and extending through the sheet. A plurality of protrusions or teeth 425 are located adjacent slot 420. At the opposite end of stent 410 is second longitudinal edge 430 which has a plurality of apertures 435 located adjacent edge 430. In order to roll the stent, second longitudinal edge 430 is coiled up and inserted in elongated slot 420 until the stent is tightly coiled to a reduced diameter form and slid onto the balloon portion of a catheter. When the stent is loaded onto a balloon portion of a catheter, it has a low profile and can be easily transported through a body

lumen and into, for example, the coronary artery. Once the stent is positioned in a coronary artery, the balloon portion of the catheter is radially expanded which in turn radially expands stent 410. As the stent expands, apertures 440 come in contact with teeth 425 and engage each other in an interlocking relationship. Stent 410 has tendency to return to its coiled state, thus, the interlocking relationship of the apertures and teeth prevent the stent from contracting.

The stent of the present invention, in particular the embodiments of Figs. 19-29, are designed to engage in a sure manner, and, once engaged, to stay engaged with a high degree of reliability.

In all of the stent embodiments disclosed, it is desirable to minimize the number of protrusions that line the inner surface of the stent, to minimize the possibility of fibrin accumulation and thrombosis. To this end, the inner surface of the stent (the outermost edge) may have fewer rows of protrusions along the longitudinal edge, to maintain a smooth interior by minimizing the protrusions exposed inside the stent, that is, to minimize the number of protrusions that are not engaged.

The stent may be deployed in a vessel by any suitable means, such as with a stent delivery catheter formed from an angioplasty balloon catheter.

Again, it should be understood that while in the above embodiments the protrusions on the body were formed from the body of the stent, in general the protrusions may be formed in any manner, including by adding the protrusions to a smooth body made of the same or different material from the protrusions, or by treating the body to create a roughened surface texture, with or without apertures in the body. As before, the surface texture forming the protrusions may be formed via plasma techniques, corona techniques, molding, casting, laser machining, etching, non-laser machining, extruding, or any other technique that changes the surface texture of the body.

Although in the preferred embodiment the stent of the present invention is deployed in a vessel with a balloon catheter, any suitable means for transporting and delivering the stent may be used. Furthermore, other modifications can be made to the present invention by those skilled in the art without departing from the scope thereof.

The stent of the present invention may be used not only in cardiovascular procedures, but also in urinary, prostate, renal, cerebral, nasal, auditory, rectal procedures and other medical procedures.

Furthermore, it should be understood that any dimensions set forth for the above embodiments are not intended to limit the invention to only those dimensions. For example, while certain dimensions might be appropriate for a stent used in a coronary artery, these same dimensions might not be suit-

able for a stent used in other areas of a patient's vasculature or body lumen. It is also understood that the drawings are not necessarily to scale.

Other modifications can be made to the present invention by those skilled in the art without departing from the scope thereof.

Claims

- 5 1. An intraluminal stent implantable in a body lumen, comprising: a plurality of rings having at least a pair of overlapping edges; a plurality of teeth on at least one of said overlapping edges; whereby said rings are expanded from a first diameter to an adjustable, enlarged diameter so that said teeth engage in an interlocking relationship to hold said rings in said enlarged diameter form.
- 10 2. An intraluminal stent implantable in a body lumen, comprising: a cylindrical body portion formed of a sheet having longitudinally extending overlapping edges; a plurality of tabs located on one edge of said sheet; a plurality of slots on said sheet corresponding with and aligning with said tabs; whereby said slots receive said tabs.
- 15 3. An intraluminal stent implantable in a body lumen, comprising: a cylindrical body portion having an axial length extending along a longitudinal direction, said cylindrical body portion formed of a sheet having a first longitudinal edge and a second longitudinal edge, an elongated slot in said sheet on said first longitudinal edge, said elongated slot adapted to receive said second longitudinal edge.
- 20 4. An intraluminal stent implantable in a body lumen, comprising: at least one strip disposed along a longitudinal direction, said strip forming a ring having overlapping edges; a slot disposed in said stent, said slot receiving said strip to form said ring.
- 25 5. An intraluminal stent implantable in a body lumen, comprising: a substantially cylindrical body portion having a length extending along a longitudinal direction, said body portion having a first edge that contains a slot extending along said longitudinal direction, and said body portion having a second edge extending along said longitudinal direction; said second edge passing through said slot; wherein when said cylindrical body portion is expanded from a first reduced diameter to a second, enlarged diameter, said at least one of said edges undergoes greater deformation than said other
- 30
- 35
- 40
- 45
- 50
- 55

edge, to create a bias so that said stent is biased to return to said first reduced diameter form.

6. An intraluminal stent implantable in a body lumen, comprising: a body portion formed from a sheet, said sheet having a first edge and a second edge parallel to said first edge, said sheet having a plurality of apertures near said first edge of said sheet and a plurality of teeth extending from said second edge of said sheet, said body portion having a substantially cylindrical shape, wherein said teeth engage said apertures, wherein said substantially cylindrical body portion has an axial length extending along a longitudinal direction, and said sheet is formed from a reticulated structure having a plurality of substantially S-shaped members, said S-shaped members having top and bottom portions, said top and bottom portions extending along said longitudinal direction, with said S-shaped members connected to one another through a plurality of interconnecting members attached to said top and bottom portions of said S-shaped members. 5

7. An intraluminal stent implantable in a body lumen, comprising a body portion formed from a sheet, said sheet having a first edge and a second edge parallel to said first edge, said sheet having a plurality of apertures near said first edge of said sheet and a plurality of teeth extending from said second edge of said sheet, said body portion having a substantially cylindrical shape, wherein said teeth engage said apertures in an interlocking manner, wherein said substantially cylindrical body portion has an axial length extending along a longitudinal direction, said sheet is formed from a reticulated structure comprising a plurality of substantially honeycomb-like members, with a plurality of gaps interrupting said honeycomb-like members to allow increased flexibility. 10

8. An intraluminal stent implantable in a body lumen, comprising a substantially cylindrical body portion having an axis extending along a longitudinal direction, said body portion formed from a sheet of material, said sheet having a pair of edges that form a spiral seam about said longitudinal direction. 15

20

25

30

35

40

45

50

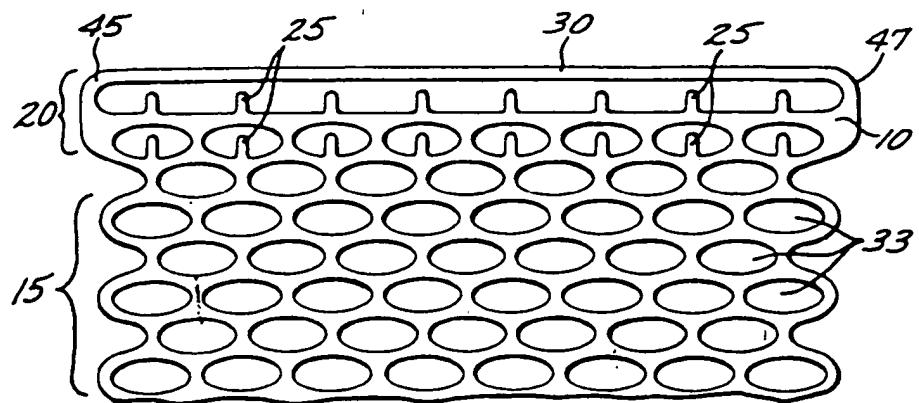


FIG. 1

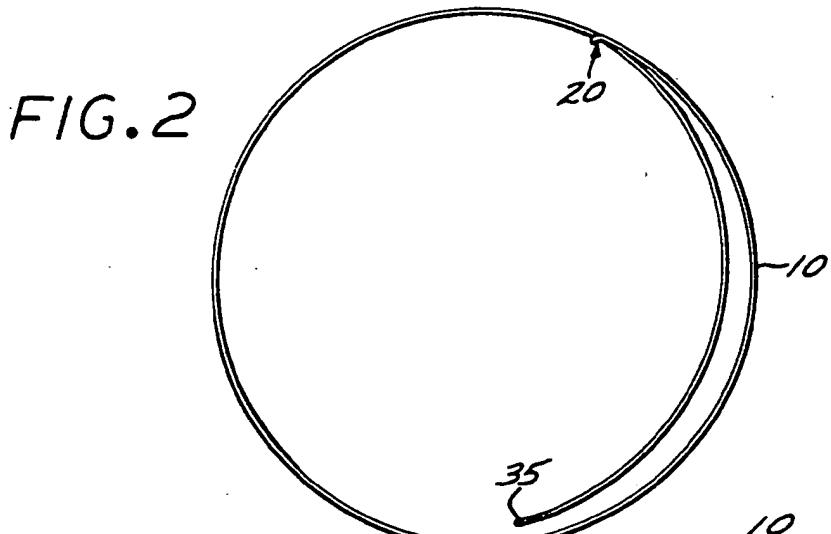


FIG. 2

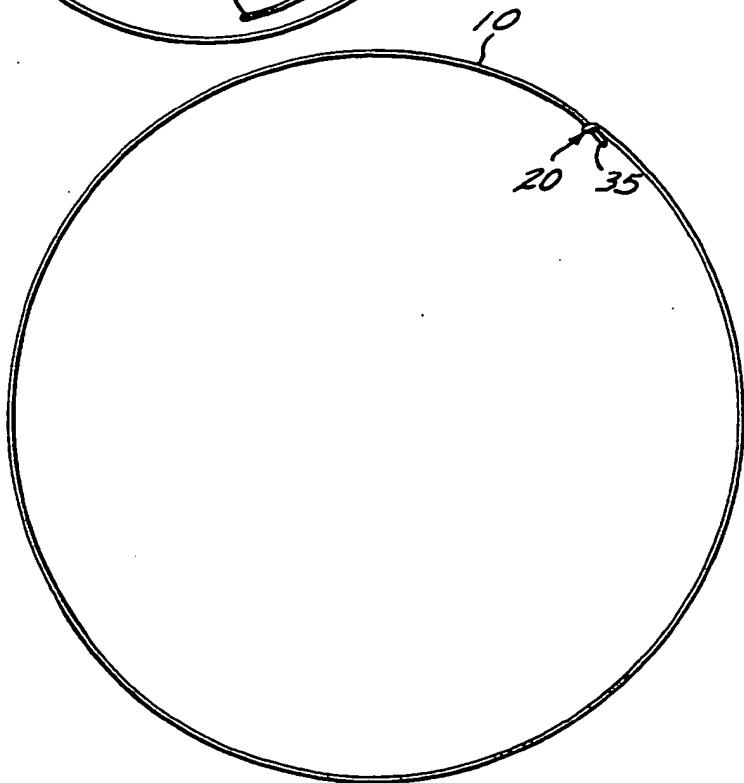


FIG. 3

FIG.4

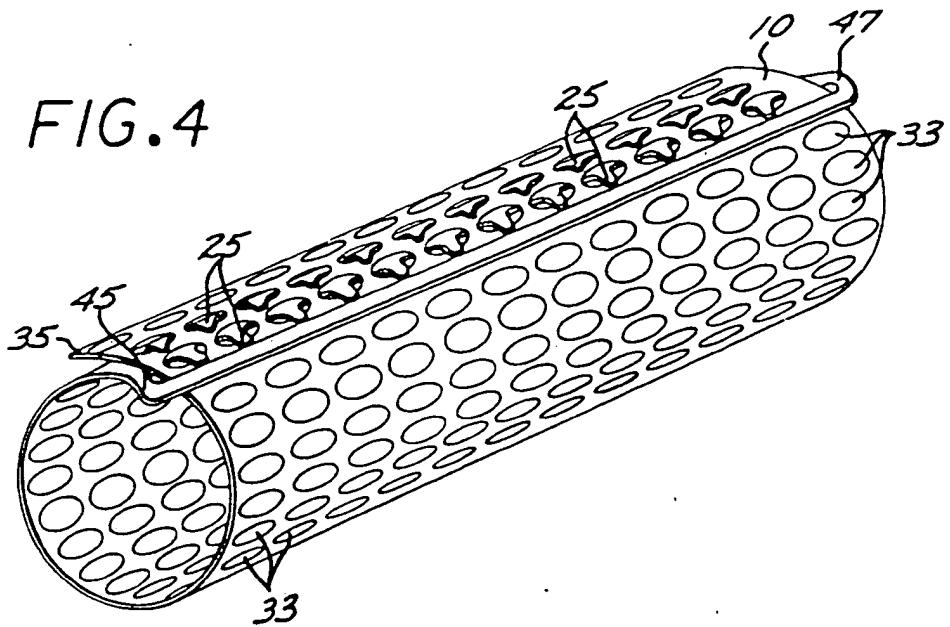


FIG.5

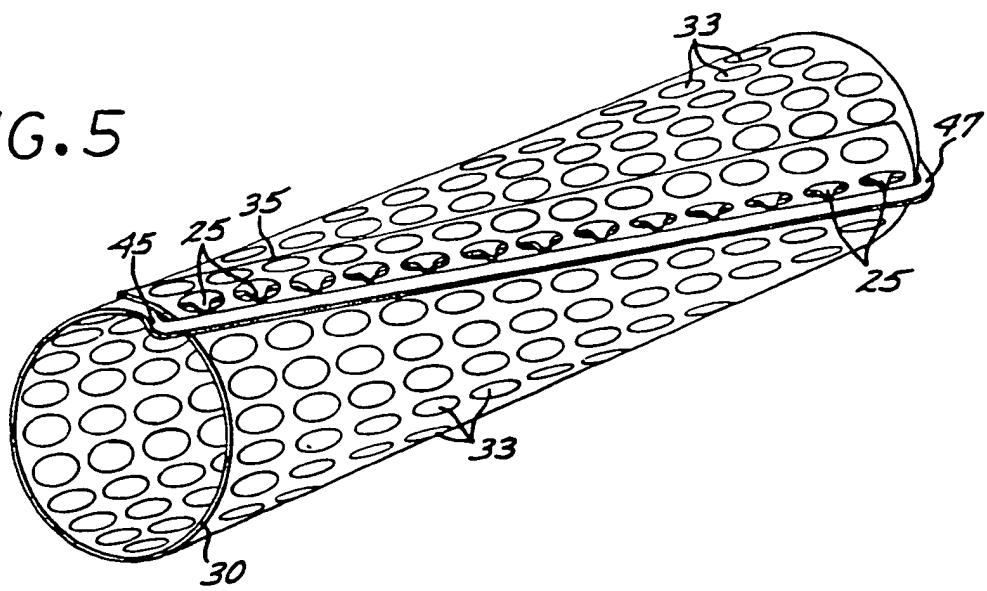


FIG. 6

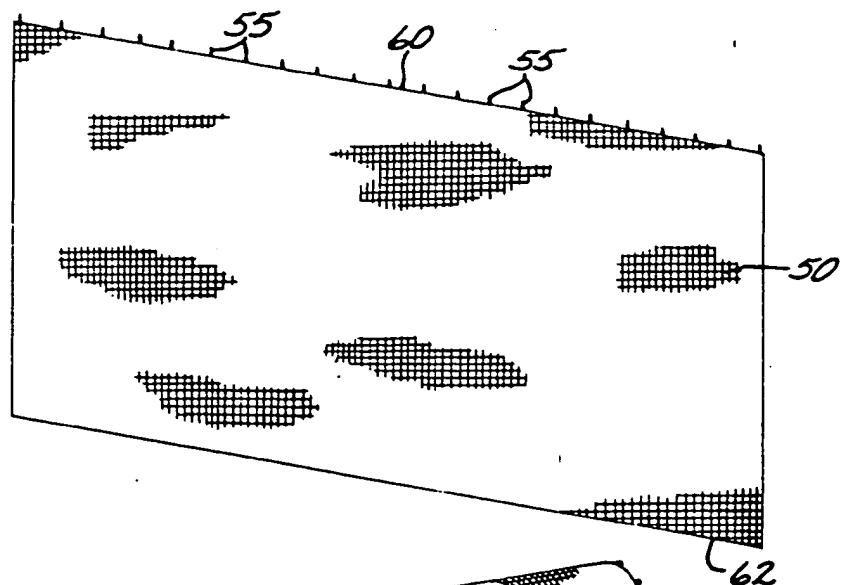


FIG. 7

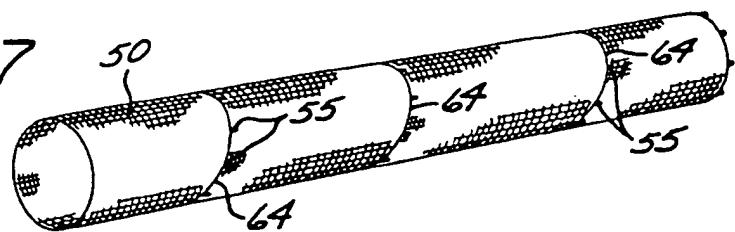


FIG. 8

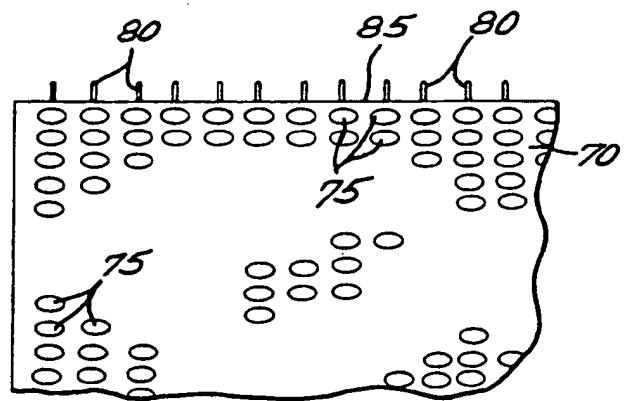


FIG. 9

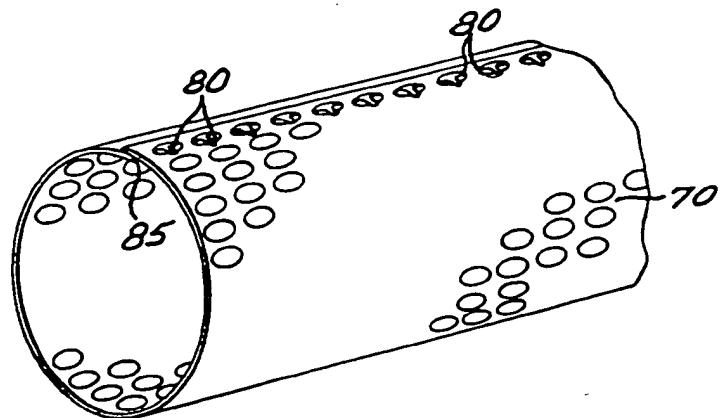


FIG.10

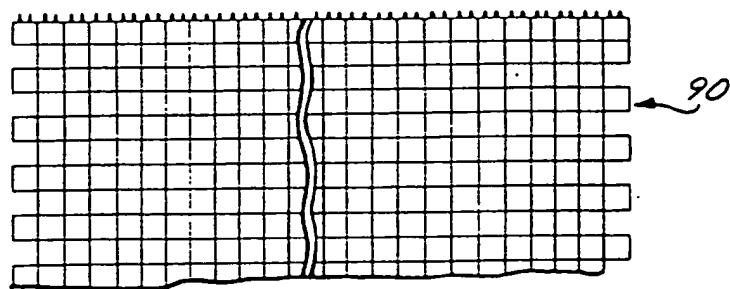


FIG.11

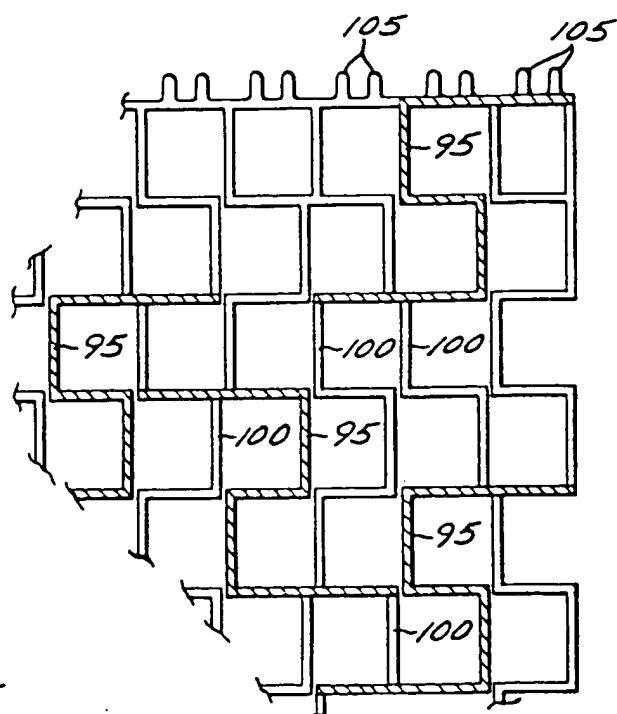


FIG.12

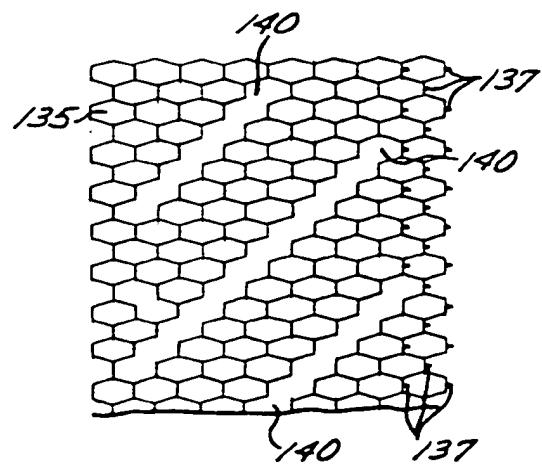
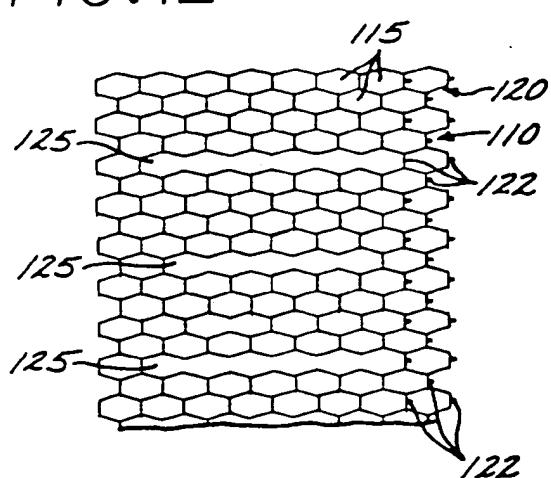


FIG.13

FIG.14

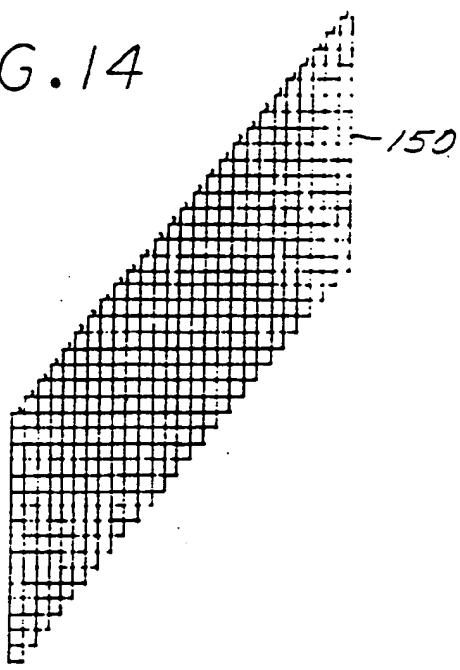
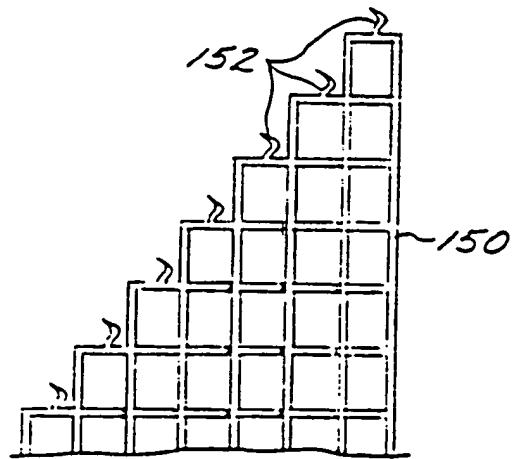
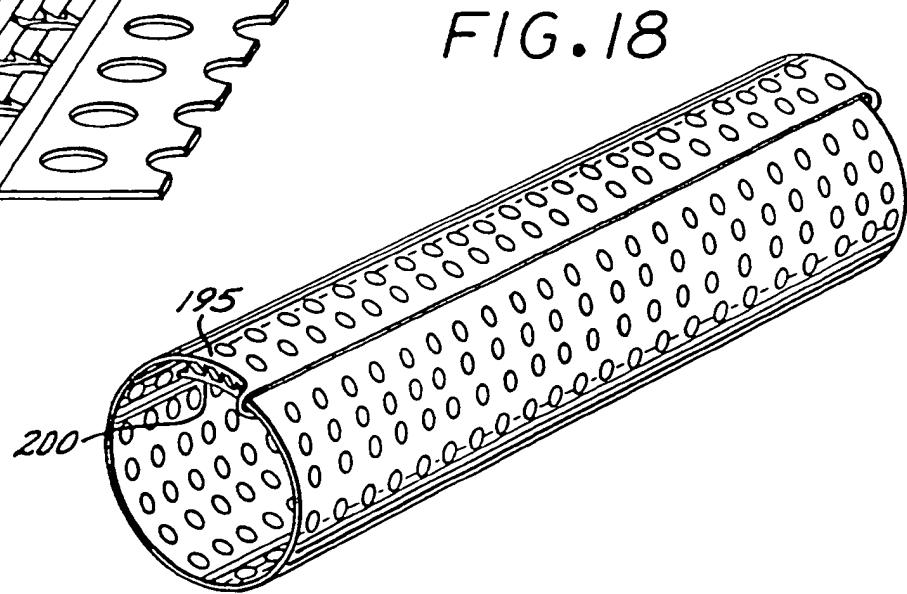
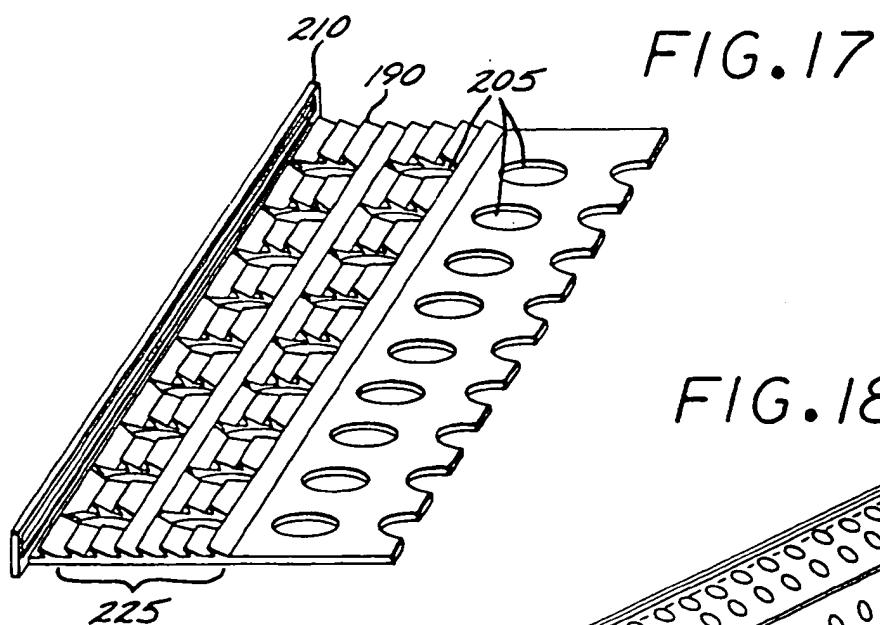
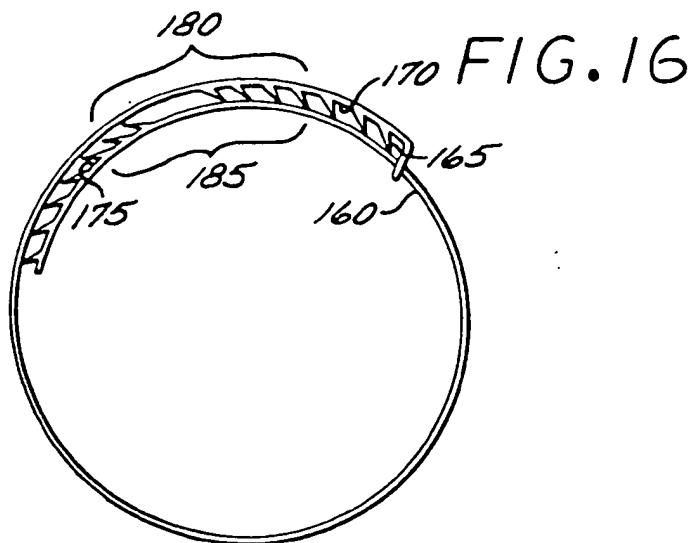


FIG.15





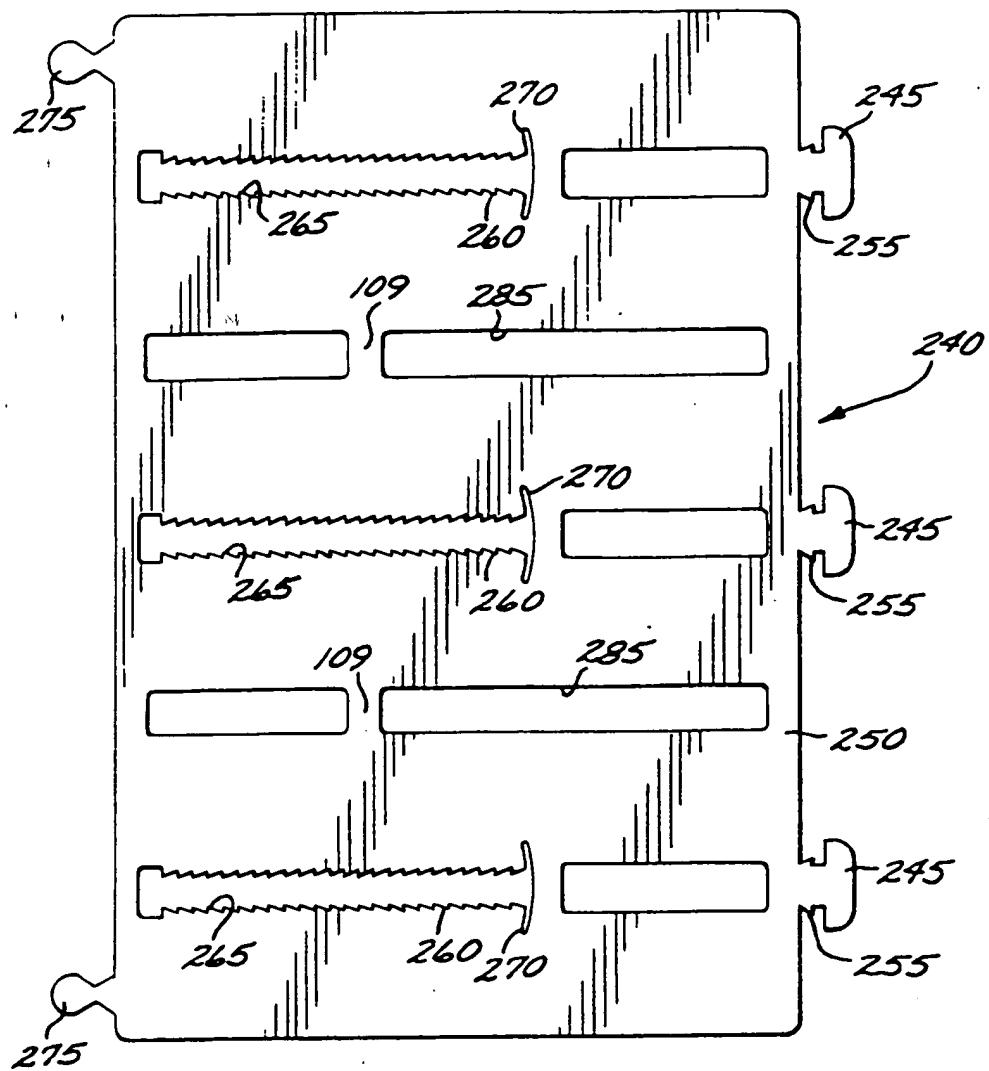


FIG. 19

FIG. 20

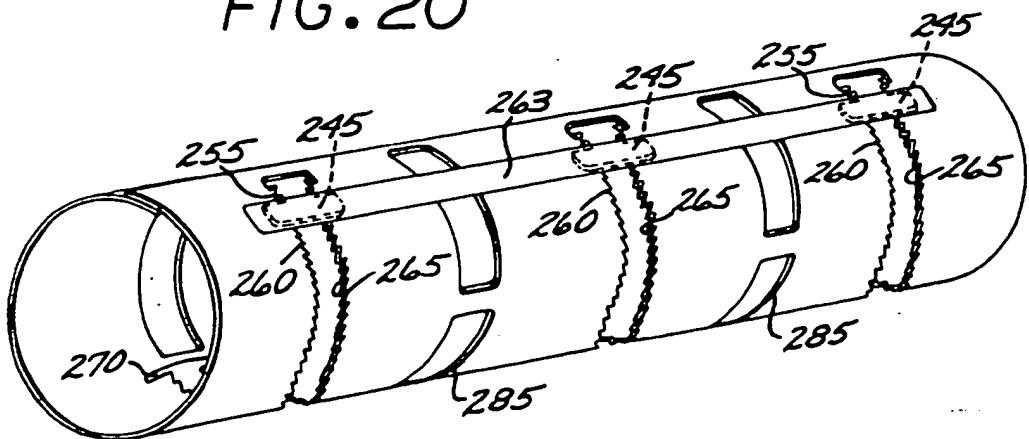


FIG.21

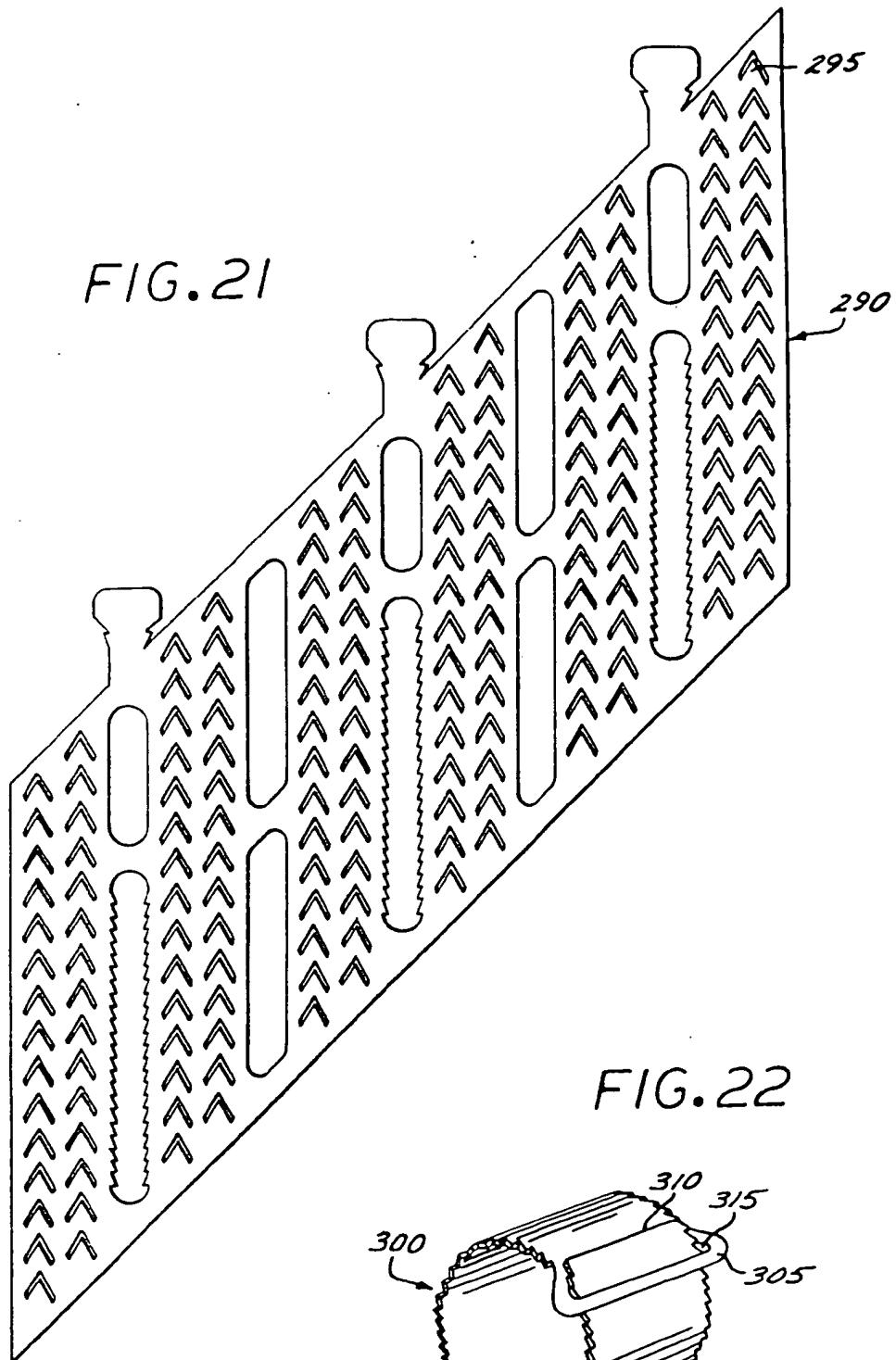
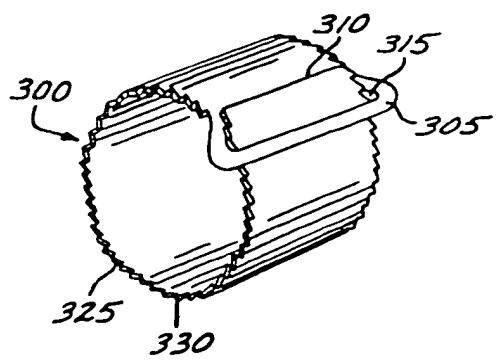
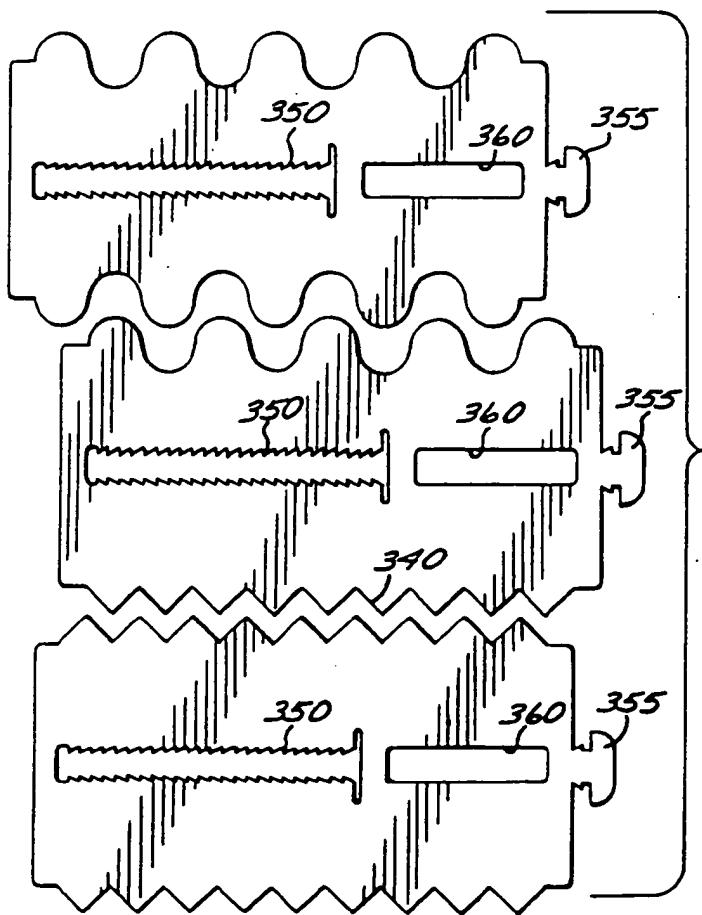
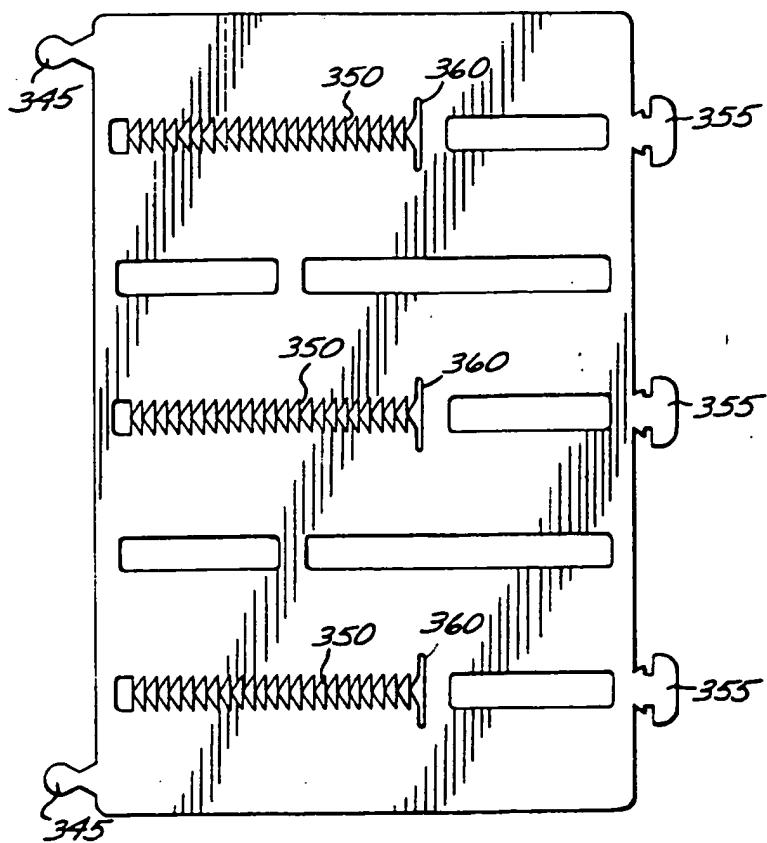


FIG.22





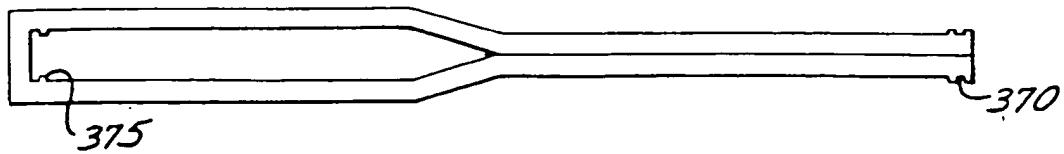


FIG. 25

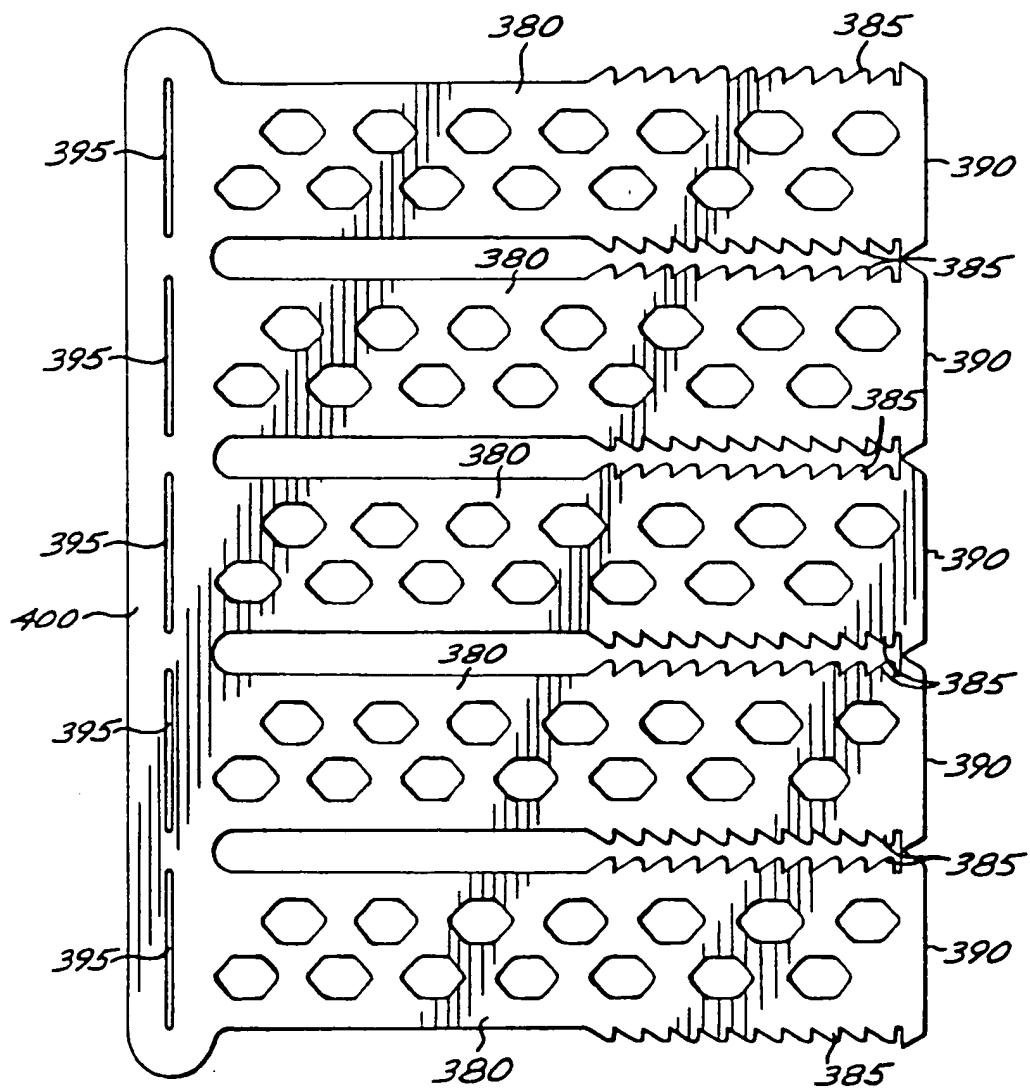


FIG. 26

FIG.27

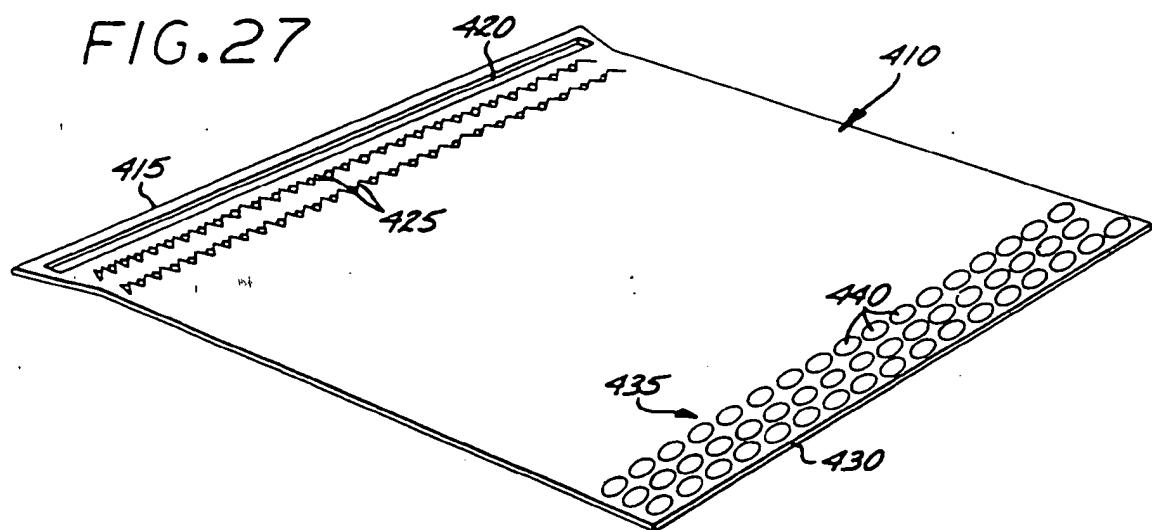


FIG.28

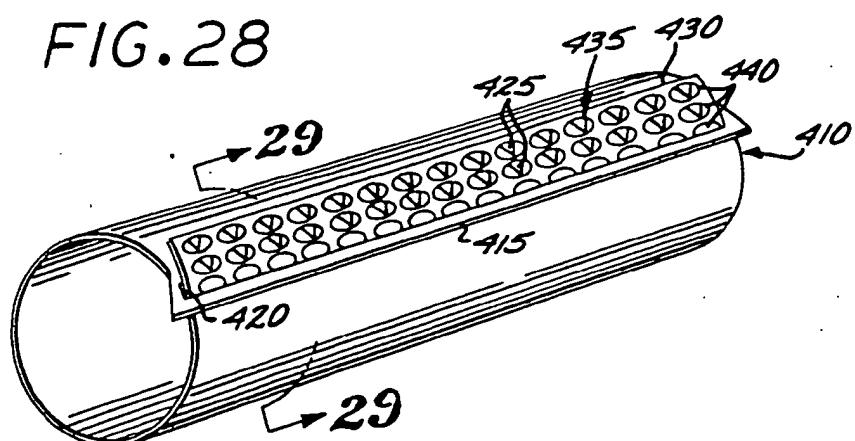
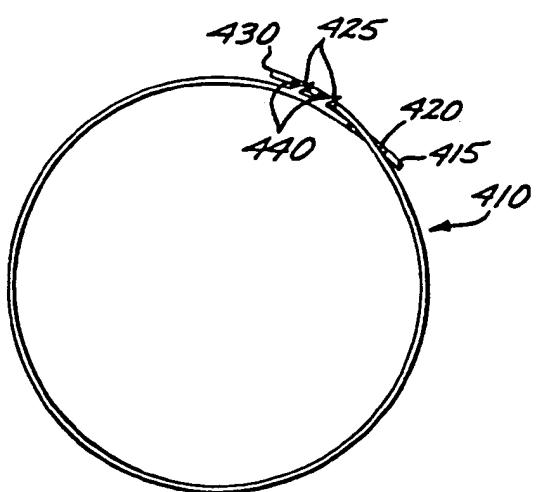


FIG.29





European Patent
Office

EUROPEAN SEARCH REPORT

Application Number

EP 94 30 2929

DOCUMENTS CONSIDERED TO BE RELEVANT			CLASSIFICATION OF THE APPLICATION (Int.CLS)		
Category	Citation of document with indication, where appropriate, of relevant passages	Relevant to claim			
X	US-A-5 100 429 (SINOFSKY) * column 10, line 22 - line 26 * ---	1	A61F2/06		
X	FR-A-2 660 562 (PEROUSE) * the whole document * ---	1,2			
X	EP-A-0 382 014 (A.C.S.) * abstract; figure 1B *	2			
A	---	1,3-5,7, 8			
X	US-A-5 158 548 (LAU ET AL) * column 5, line 49 - column 6, line 6; figures 12,13-15 *	6			
A	EP-A-0 364 787 (E.G.P) * figure 1B *	7			
A	US-A-5 007 926 (DERBYSHIRE) -----				
			TECHNICAL FIELDS SEARCHED (Int.CLS)		
			A61F		
The present search report has been drawn up for all claims					
Place of search	Date of completion of the search	Examiner			
THE HAGUE	8 July 1994	Papone, F			
CATEGORY OF CITED DOCUMENTS					
X : particularly relevant if taken alone	T : theory or principle underlying the invention				
Y : particularly relevant if combined with another document of the same category	E : earlier patent document, but published on, or after the filing date				
A : technological background	D : document cited in the application				
O : non-written disclosure	I : document cited for other reasons				
P : intermediate document	A : member of the same patent family, corresponding document				